

Remarks

Claims 1-22, 24, and 27 are pending. Claims 5, 8, 21, and 27 have been amended. Claims 13-20 are withdrawn as being drawn to a non-elected invention. Claims 23, 25, 26, and 28 have been canceled. Claims 3, 5, 6, 8, 10, 21, and 27 have been amended to more clearly claim what applicants consider to be their invention. In particular, claim 5 has been amended to recite that the vaccine does not include saponin. Support for the amendment of claim 5 can be found throughout the specification as filed, but more specifically on page 8, lines 16-26, more specifically line 21. Claims 8 and 27 have been amended to depend from claim 1. Claims 21 and 26 have been amended to depend from claims 1 and 8, respectively. Claims 3, 6, and 10 have been amended to recite "cells" instead of "cell equivalents" in order to clarify the meaning. No new matter is believed to be added.

In the Advisory Action dated April 25, 2003, the Examiner states that "additionally, amended claim 1 and claims 2-12 (which depend from claim 1) would raise new 112 issues. New issues would include a New Matter rejection under 35 U.S.C. 112, first paragraph for the negative limitation "...wherein the vaccine does not include saponin...".

Applicants respectfully traverse. MPEP section 2173.05(i) states that "The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention...Any negative limitation or

exclusionary proviso must have basis in the original disclosure. *If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims.*" (Emphasis added.) In the case of saponin, it is positively recited in the specification. Page 8, lines 14-21 reads "In a specific embodiment, suitable adjuvants can be chosen from the following group: mineral, vegetable or fish oil with water emulsions...saponin..." Therefore, the specification clearly positively recites saponin as an alternate element in the specification. Therefore, saponin may be explicitly excluded in the claims.

Moreover, in *In re Johnson*, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977), the CCPA held that a claim to a genus with the limitation of a negative proviso that did not appear in the original specification complied with the written description requirement (for the purpose of establishing benefit of an earlier filing date to overcome a prior art rejection based on applicants' earlier foreign-filed patent). The negative proviso, which was inserted to avoid having the claim read on a lost interference count, literally excluded more than the two species disclosed in the application (and the full scope of the negative proviso was clearly understood and acknowledged by the court; *ibid* at Note 12). The court stated:

The notion that one who fully discloses and teaches those skilled in the art how to make and use a genus and numerous species there within, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result in a hypertechnical application of legalistic prose relating to that provision of the statute.

Ibid at 1019.

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The holding in *Johnson* was affirmed by the court in *In re Driscoll*, 562 F.2d 1245, 1250, 195 USPQ 434 (CCPA 1977), which observed (with regard to the court's reversal, in *Johnson*, of the Patent Office's refusal to grant Johnson's application the benefit of an earlier filing date, based on an alleged lack of written description, in the original application, for the negative proviso):

In reversing the rejection, the court there observed that the applicants were merely excising the invention of another, to which they were not entitled, rather than creating an artificial subgenus or claiming new matter.

Ibid at 1250.

Therefore, Applicant asserts that the recitation of vaccine not including saponin does not constitute new matter and should not be rejected under 35 U.S.C. 112, first paragraph for the negative limitation, as alluded to by the Examiner in the Advisory Action.

As disclosed above, support for inclusion or exclusion of saponin in the vaccine of the present invention can be found on page 8, lines 16-26, of the specification as filed. Importantly, Howard *et al.* includes saponin, particularly it includes Quil A (see Attachment A of the Response to Office Action mailed December 18, 2002, indicating that Quil A is a saponin). Moreover, Howard *et al.* states that "...immune responses could be improved for ...the mycoplasmas...by the use of Quil A rather than oil adjuvant (Howard *et al.*, 1987; page 372, second column, starting at the 3rd line). As it is only over the allegedly effective vaccine of Howard *et al.* that earlier pending claims 1-4 and 21 were rejected under 35 U.S.C. § 102(b), and

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over the combination of Howard *et al.* in view of Poumarat *et al.* that claims 5-12 were rejected over 35 U.S.C. § 103(a); Applicants submit that as amended, pending claims 1-12, 21, 22, 24, and 27, which exclude any saponin, are not anticipated by Howard *et al.* Furthermore, since neither Howard *et al.* nor Poumarat *et al.* teach or suggest a vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species wherein the vaccine does not include saponin, a combination of Poumarat *et al.* and Howard *et al.* cannot suggest the present invention. Accordingly, the combination of Poumarat *et al.* with Howard *et al.* cannot provide the invention as claimed in claims 1-12, 21, 22, 24, and 27.

Applicants therefore request removal of this basis for rejection and allowance of claims 1-12, 21, 22, 24, and 27 to issue.

Pursuant to the above amendments and remarks, consideration and allowance of the pending application is believed warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

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Respectfully submitted,

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5-19-03

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